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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/040,070	10/23/2001	Bradley L. Christenson	19654-238898	9400

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EXAMINER	
BERKO, RETFORD O	
ART UNIT	**PAPER NUMBER**
1615	5

DATE MAILED: 07/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/040,070	Applicant(s) CHRISTENSON ET AL.	
	Examin r Retford Berko	Art Unit 1615	

-- The MAILING DATE of this communication app ars on the cover she t with th correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-22 is/are pending in the application.

4a) Of the above claim(s) 10-22 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-9 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claim1 -9, drawn to granule and tablet comprising the granule, classified in class 424, subclass 489,499,464.

II. Claim10-22, drawn to tablet containing coated granules and process of making, classified in class 424, subclass 494, 495,470.

The inventions are distinct different from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions (1) create different products (2) the methods do not use the product of Group I (3) different classification in the art and (4) patentably distinct inventions.

During a telephone conversation with Attorney Busse on June 23,2003 a provisional election was made with traverse to prosecute the invention of Group I, claim1-9. Affirmation of this election must be made by applicant in replying to this Office action.

Claim10-22 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Group II, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No.5.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 1-9 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claim1-9 of copending Application No. 10/076,892. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented. The scope of Claims 1-9 teaches that the invention is a granule comprising of potassium chloride crystals and ethyl cellulose. The scope of Application No.10/076,892 also teaches that the invention is a granule comprising potassium chloride crystals with cellulose ether. Clearly, this represents the same scope of invention.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1, 3, 5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Osawa et. al. (USPN 3,873,588). The claims are drawn to an extended release tablet comprising granules of potassium chloride and a thermoplastic cellulose ether, where the ether is ethyl cellulose. Osawa et. al. teaches an extended release tablet comprising

granules of potassium chloride and ethyl cellulose (col. 5, lin 45-49; col. 13, lin 3-8). These disclosures render the claims anticipated.

2. Claims 1, 3 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Lipmann et. al. (USPN 4,259,315). Claims 1, 3 and 5 are drawn to a granule comprising potassium chloride and a thermoplastic cellulose ether, where the thermoplastic ether is ethyl cellulose. The ethyl cellulose has a viscosity of 10-30 cP.

Lipmann teaches a controlled release formulation comprising granules of potassium chloride and a thermoplastic cellulose ether. The cellulose ether of the reference is preferably ethyl cellulose and has a viscosity of 22 cP (Abstract; clo. 4, lin 40-55). These disclosures render the claimed invention anticipated.

3. Claims 1-5 are rejected under 35 U.S.C. 102(b) as being anticipated by Chen (USPN5,397,574). Claims 1-5 include granules containing potassium chloride with a mesh size between 20 and 60 and ethyl cellulose having viscosity between 10 and 30 cP.

Chen teaches a controlled release tablet of potassium chloride, where the granules that make up the tablet are coated with ethyl cellulose (Abstract). Chen further teaches that the ethyl cellulose of the invention has a viscosity of 10 cP while the potassium chloride particles have a mesh size between 20 and 50 (col. 3, example 1). These disclosures render the claims anticipated.

4. Claims 1-5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated in view of Hsiao et al (USPN 4,863,743). Claims 1-4 are drawn to a granule comprising potassium chloride and a thermoplastic cellulose ether, where the thermoplastic ether is ethyl cellulose. The ethyl cellulose has a viscosity between 10-30 cP, while the potassium chloride crystals have a mesh size between 20-60. Claims 5 and 8 are drawn

to an extended release tablet made from the granules where the tablet contains 10, 15 or 20 mEq of potassium.

Hsiao et. al. teaches an extended release tablet containing granules comprising potassium chloride and ethyl cellulose. The ethyl cellulose used by the reference has a viscosity ranging from 6-40 cP. The tablet contains 20 mEq of potassium, and would be administered to a patient needing potassium ion supplementation therapy (col.3, lin. 54-60; col. 4, lin. 51-68, col.5, lin. 43-56). These disclosures render the claims anticipated.

Claim Rejections-35 USC Sec. 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The relevant part of the factual inquiries set forth in Graham v. John Deere & Co., 383 U.S. 1, 148 USPQ 459 (1966) that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and content of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue
3. Resolving the level of ordinary skill in the pertinent art
4. Considering objective evidence present in the application indicating obviousness or non-obviousness.

Claims 1-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsiao et.al. (USPN 4,863,743). Claims 1-4 are drawn to a granule comprising potassium chloride and a thermoplastic cellulose ether, where the thermoplastic ether is ethyl cellulose. The ethyl cellulose has a viscosity between 10-30 cP, while the potassium chloride crystals

have a mesh size between 20-60. Claims 5-9 are drawn to an extended release tablet containing the granules of Claims 1-4. The claims recite that the tablet is substantially free from surfactants and other processing aids and agents. The claims recite specific concentrations and ranges of the essential components.

As discussed above, Hsiao et. al. teaches the essential elements of the claimed invention. The examples of the reference include other excipients and that the excipients are completely optional. Barring a comparative showing of unexpected results and criticality to the composition being substantially free from surfactants and other agents, the examiner posits that these limitations do not impart patentability as they do not distinguish the claimed invention from the prior art; by the presence of a different property and/or result.

Claims 7-9 are drawn to tablets containing specific concentrations of potassium chloride and ethyl cellulose. The claims specifically recite that the tablets have 75.3% by weight of potassium and 15.5% by weight of ethyl cellulose. It would be obvious to one of ordinary skill in the art to modify the formulation to achieve the optimal results recited in the specification. Furthermore, applicant is reminded that merely reciting the optimal working ranges in a composition does not impart patentability, when the general conditions of the composition are met. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. (In re Aller, 220 F.2d 454, 105 USPQ233, 235 (CCPA 1955)). Also, the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of compositions with various amounts of the active ingredient is within the level of skill of one having ordinary skill in the art at

the time of the invention. It is also held that mere selection of proportions and ranges is not patentable absent a showing of criticality (In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971)).

Furthermore, one of ordinary skill would be motivated to modify the teachings of the reference to achieve an optimal formulation. As the formulation does not require furthe rexcipients, a skill artisan would be motivated to formulate a tablet from granules of potassium chloride and ethyl cellulose without of other components, in order to achieve an optimal release profile. It would be prima facie obvious to a skilled artisan at the time of applicant's invention to modify the teaching and suggestions in the reference because a person of ordinary skill in the formulation art desires optimization of ingredients with an expected result of a controlled release tablet containing potassium chloride granules and ethyl cellulose.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Retford Berko whose telephone number is 703-305-4442. The examiner can normally be reached on M- F 8:00a.m-5:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-9903 for regular communications and 703-746-9903 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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